UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/844,336	04/18/1997	PAMELA R. CONTAG	8678-004-999	7227

7590 07/21/2006

ROBINS & PASTERNAK LLP
1731 EMBARCADERO ROAD
SUITE 230
PALO ALTO, CA 94303

EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 07/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/844,336	CONTAG ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *09 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9,21,22 and 25-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-9,21,22 and 25-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on 5-9-2006 is acknowledged. Claims 1, 9 and 26 have been amended. Claims 1, 3-9 21, 22 and 25-27 are pending and currently under examination.

New Claim Objections

Claim 1 is objected to because of the following informalities: said claim, as amended, contains confusing claim language. Appropriate correction is required.

It is suggested that the claim language "wherein said extracellular ligand-specific moiety comprises an antibody or a derivative thereof wherein said antibody or derivative thereof binds to said selective substance..." in lieu of "wherein said extracellular ligand-specific moiety comprises an antibody or a derivative thereof and which antibody or derivative thereof binds to said selected.

Claim Rejections Withdrawn

The new matter rejection of claims 1, 3-9 21, 22 and 25-27 are rejected under 35 U.S.C. 112, first paragraph, based on the recitation in claim 1 of "a transmembrane fusion protein comprising an extracellular ligand-specific moiety derived from an antibody and an intracellular enzymatic signal transforming domain" is withdrawn in light of the amendment thereto.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "derived from an antibody" is withdrawn in light of the amendment thereto.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "selectively recognizes" is withdrawn in light of the amendment thereto.

The rejection of claim 9 under 35 U.S.C. 112, second paragraph, for lacking antecedent basis for the limitation "said substance" in line 1 is withdrawn in light of the amendment thereto.

The rejection of claim 26 under 35 U.S.C. 112, second paragraph, for lacking antecedent basis for the limitation "said fusion protein" in line 1 is withdrawn in light of the amendment thereto.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, for lacking antecedent basis for the limitation "said intracellular transforming domain" in line 1 is withdrawn in light of the amendment thereto.

The rejection of claims 1, 3-9 21, 22 and 25-27 under 35 U.S.C. 103(a) as being unpatentable over Contag et al. (U.S. Patent 5,650,135 – IDS filed on 10-5-98) in view of Georgiou et al. (U.S. Patent 5,348,867 – IDS filed on 1-22-99) is withdrawn. Applicant's arguments have been fully considered and deemed persuasive.

New Grounds of Rejection

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-9, 21-22 and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the term "derivative thereof". It is unclear what is meant to be encompassed by said term as it is not explicitly defined in the specification. The specification at page 15, lines 9-15 merely recites a non-limited list of things encompassed by said term. Consequently, it is impossible to determine the metes and bounds of the claimed invention.

Claim 7 recites the limitation "said intracellular signal transforming domain" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 21 recites the limitation "said signal transforming domain" in line 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 25 recites the limitation "said enzyme signal transforming domain" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-9 21, 22 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menzel et al. (U.S. Patent 5,521,066) in view of Georgiou et al. (U.S. Patent 5,348,867 – IDS filed on 1-22-99)

The instant claims are drawn to a biodetector comprising a transmembrane fusion protein comprising an extracellular ligand-specific moiety comprising an antibody or a derivative thereof and an intracellular enzymatic signal-transforming domain (i.e. signal-converting element) optionally coupled to a reporter gene (luciferase) via a responsive element (transcription activation element) and a transducer. Said biodetector may further comprise a bacterial cell.

Menzel et al. disclose a transmembrane fusion protein comprising a ligand binding domain, a cytoplasmic toxR DNA binding region, a hydrophobic ToxR transmembrane region and a reporter gene operatively linked to the ctx operon (see column 1, line 65 to column 2, line 6). Menzel et al. further disclose that when a ligand binds to the ligand binding domain, the cytoplasmic domain of the fusion protein to undergo a conformational change which induces binding to the promoter region of the reporter gene (see column 2, lines 35-44). Finally, Menzel et al. disclose that their fusion protein can be used to generate signal using a variety of ligand-binding domains (see column 2, lines 15-16) and that any reporter gene known in the art can be

used with the disclosed fusion protein (see column 4, lines 38-42) and that the disclosed fusion proteins can be expressed in bacterial hosts (see column 7, lines 7-8).

Menzel et al. differs from the claimed invention in that they do not explicitly disclose the use of the antibodies or derivatives thereof or the specific use of luciferase as the reporter.

Georgiou et al. disclose methods for the recombinant expression of heterologous proteins on the surface of bacteria (see abstract) including the expression of scFv (see column 6, lines 25-26).

Since Menzel et al. disclose that a variety of ligand binding domains can be used in their transmembrane fusion protein, it would have been obvious to one of skill in the art to use the heterologous scFv disclosed by Georgiou et al. in order to take advantage of the increase in specificity, diversity and ease of production associated with the resulting fusion protein (biodetector).

Conclusion

No claim is allowed.

Claims 25-26 are free of the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ROBERT A. ZEMAN
PRIMARY EXAMINER

July 18, 2006